

IREx Agreement Instructions Template

Purpose: This email is sent to relying site HRPPs (Human Research Protection Program) and Study Team members to notify them about the agreement requirements for a study.

Email Subject: Action Required: Please Complete Agreement(s) for sIRB study

Attachments (if applicable):

- Other reliance agreement template
- Indemnification agreement template
- Additional instructions provided by sIRB

Email Body:

Dear HRPP(s) and Site Investigator,

This email contains **instructions for executing incomplete agreements** for the study below where **[Investigator Name]** an investigator at **[Site Name]** (FWA: #####) has been listed on the following study in IREx.

Study Title	[Study title]
Reviewing IRB	[SIRB (single IRB) site]
Reviewing IRB Contact	[Primary SIRB contact name and email]
Study Manager	[Study manager(s) name and emails]

As a first step towards relying on [Reviewing IRB Site Name], please execute the incomplete items below.

Agreement/Resource	Status
If offering SMART: SMART IRB Agreement: A national, master reliance agreement supporting single IRB review. If other reliance agreement is offered: Or [Other Reliance Agreement (ORA) Name]	Completed / Incomplete – The HRPP can follow the steps to join SMART IRB here . If offering SMART IRB & ORA, but neither is complete: Incomplete – The HRPP can follow the steps to join SMART IRB here or execute the reliance agreement attached. Send questions and executed agreements to [Primary Reviewing IRB Contact name and email].
If indemnification agreement is required: [Indemnification Agreement Name]	Completed / Incomplete – The indemnification agreement is attached. Send questions and executed agreements to [Primary Reviewing IRB Contact name and email].
IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. <i>This is a web-based platform, not a reliance agreement.</i>	Completed / Incomplete – A HRPP administrator, director, or manager can initiate access here .

After your site has completed all the items above and the initial protocol has been approved by the Reviewing IRB, additional instructions will be sent regarding next steps.

Thank you,

[Name of user sending the agreement request]

[Email of user sending the agreement request]

IREx Single IRB Instructions Template

Purpose: This email is sent to relying site HRPPs (Human Research Protection Program) and Study Team members to notify them about the study and to give study teams access to lead site approval documents in IREx.

Email Subject: IREx Access and Single IRB Instructions

Attachments (if applicable):

- Other reliance agreement template
- Indemnification agreement template
- Additional instructions provided by sIRB

Email Body:

Dear HRPP(s) and Study Teams,

This email contains instructions for completing the single IRB process for the study below.

[Investigator Name] has been listed as an investigator at **[Site Name]** (FWA: #####). All study team members included on this email now have access to the study in IREx.

STUDY & PRIMARY CONTACTS

Study Title	[Study title]
Study Link	[IREx study link]
Reviewing IRB	[SIRB (single IRB) site]
Reviewing IRB Contact	[Primary SIRB contact name and email]
Study Manager	[Study manager(s) name and emails]

NEXT STEPS

If lead initial is published: The overall/lead site approval is available in IREx. Use these documents to prepare your local submission and initiate the reliance process at your site.

If lead initial is NOT published: The overall/lead site approval is NOT yet available in IREx. You will receive another email when it is posted.

1. LOCAL HRPP facilitates agreement execution.

The study requires the following items to be completed, which can be facilitated by the local HRPP, as needed:

Agreement/Resource	Status
If offering SMART: SMART IRB Agreement: A national, master reliance agreement supporting single IRB review. If other reliance agreement is offered: Or [Other Reliance Agreement (ORA) Name]	Completed / Incomplete – The HRPP can follow the steps to join SMART IRB here . If offering SMART IRB & ORA, but neither is complete: Incomplete – The HRPP can follow the steps to join SMART IRB here or execute the reliance agreement attached. Send questions and executed agreements to [Primary Reviewing IRB Contact name and email].
If indemnification agreement is required: [Indemnification Agreement Name]	Completed / Incomplete – The indemnification agreement is attached. Send questions and executed agreements to [Primary Reviewing IRB Contact name and email].

<p>IRB Reliance Exchange (IREx): A single IRB documentation and communication portal. <i>This is a web-based platform, not a reliance agreement.</i></p>	<p>Completed / Incomplete – A HRPP administrator, director, or manager can initiate access here.</p>
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2. STUDY TEAM prepares local consent form and submits to local HRPP for review.

- a. If applicable for the study, review the approved informed consent template(s) in IREx and insert your site-specific information.
- b. Seek guidance from your HRPP/Research Office/IRB regarding what needs to be submitted to your local HRPP to rely on the Reviewing IRB. **Most HRPPS require a local submission to complete their documentation in IREx.**

3. If capturing local considerations in IREx: STUDY TEAM & HRPP provide documentation in IREx.

STUDY TEAMS: You will receive an email when the **PI Survey** can be completed in IREx.

- The coordinator can complete the PI Survey on behalf of the PI, but the PI must attest to the PI Survey after completion and if edits are made.
- If the study involves consent forms, they are uploaded to the PI Survey after the local HRPP has reviewed them.

HRPP: If you have not received a local submission for this study, consider educating your local investigator about initiating reliance at your institution. When ready, login to IREx and complete the following steps:

- a. **Register** to confirm your site’s engagement on this study. *This is not an indication of reliance.*
- b. **Confirm the Institutional Profile.**
- c. **Indicate Reliance** by accepting the Study-Specific Reliance Plan (SSRP), the sIRB’s plan for handling HIPAA, auditing, reporting, and other flexible parts of the SMART IRB Agreement.
- d. **Complete the Human Research Protections (HRP) Survey**, which captures *study-specific* considerations for your site (e.g., applicable state or local laws, regulations, study team qualifications, etc.) that might affect the conduct or approval of the research at your site.
- e. **Review PI Survey (optional)**, which captures your local consent and specific processes regarding the study conduct at your site.

3. If NOT capturing local considerations in IREx: HRPP provides documentation in IREx.

STUDY TEAMS: You have no actions to complete in IREx.

HRPP: Login to IREx and complete the following steps:

- a. **Register** to confirm your site’s engagement. *This is not an indication of reliance.*
- b. **Confirm the Institutional Profile.**
- c. **Indicate Reliance** by accepting the Study-Specific Reliance Plan (SSRP), the sIRB’s plan for handling HIPAA, auditing, reporting, and other flexible parts of the SMART IRB Agreement.

After all steps are completed, your site will be submitted to the Reviewing IRB for review. HRPPs and study teams will receive an email notification from IREx when your site’s approval is available in IREx.

Need Help?

Access the user quick guides and other materials from the [IREx Participating Site HRPP Resources](#) and [IREx Participating Study Teams Resources](#).

Thank you,

[Name of user notifying the site]

[Email of user notifying the site]